ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

4545 CREEK ROAD
CINCINNATI, OH 45242-2839

K 012176

OCT - 1 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY:
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

CONTACT:
Ruth Ann Wood
Senior Regulatory Affairs Associate
Telephone: 513/337-3468
FAX: 513/337-1444

DATE PREPARED:
July 11, 2001

NAME OF THE DEVICE:
UltraCision® Harmonic Scalpel® Blades with Protective Sleeve
Classification LFL

PREDICATE DEVICE:
UltraCision® Harmonic Scalpel® Blades with Protective Sleeve

DEVICE DESCRIPTION:
The UltraCision Harmonic Scalpel is an ultrasonically activated surgical blade with a protective sleeve. These instruments are used to cut and coagulate soft bodily tissues and structures in many surgery procedures.

INTENDED USE/INDICATION FOR USE:
The UltraCision Harmonic Scalpel is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, gynecological ENT (Ears, Nose, Throat), including tissues of the soft palate, oral structures and oropharyngeal airway, and thoracic surgery including mobilization of the Internal Mammary Artery (IMA).

TECHNOLOGICAL CHARACTERIZATION:
The UltraCision Harmonic Scalpel is a medical device that uses ultrasonic energy to cause mechanical vibrations to cut and coagulate soft tissues.

PERFORMANCE DATA:
All previously submitted bench testing and animal studies demonstrated satisfactory performance in cutting and coagulation. The clinical information demonstrated satisfactory performance for the expanded indication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Ms. Ruth Ann Wood
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K012176
Trade/Device Name: UltraCision®Harmonic Scalpel® Blades with Protective Sleeve
Regulation Number: 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: LFL
Dated: July 11, 2001
Received: July 12, 2001

Dear Ms.Wood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K 012176

DEVICE NAME: Ultra Cision Harmonic Scalpel Blades with Protective Sleeve

INDICATIONS FOR USE:

The Harmonic Scalpel is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpel in general, gynecologic, ENT (Ears, Nose, Throat), ***including tissues of the soft palate, oral structures, and oropharyngeal airway,*** and thoracic surgery, including mobilization of Internal Mammary Artery (IMA).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANTOHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter-Use** ___
(Per 21 CFR 801.109) **(Optional Format)**

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012176